

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF MISSISSIPPI
SOUTHERN DIVISION**

**AbbVie Inc. (a Delaware corporation);
Allergan, Inc. (a Delaware corporation);
Durata Therapeutics, Inc. (a Delaware
corporation); AbbVie Products LLC (a
Georgia limited liability company); Aptalis
Pharma US, Inc. (a Delaware corporation);
Pharmacyclics LLC (a Delaware limited
liability company); Allergan Sales, LLC (a
Delaware limited liability company)**

PLAINTIFFS

VS.

CIVIL ACTION NO. 1:24-cv-00184-HSO-BWR

**LYNN FITCH, in her official capacity
as the ATTORNEY GENERAL OF THE STATE
OF MISSISSIPPI**

DEFENDANT

**MEMORANDUM OF AUTHORITIES IN SUPPORT OF DEFENDANT ATTORNEY
GENERAL LYNN FITCH’S RESPONSE IN OPPOSITION TO PLAINTIFFS’
MOTION FOR PRELIMINARY INJUNCTION**

INTRODUCTION

For the reasons explained in this Court’s Memorandum Opinions and Orders in *Novartis Pharm. Corp. v. Fitch*, No. 1:24-cv-00164-HSO-BWR [Dkt. #29] (“*Novartis*”), and *Pharm. Research & Mfrs. of Am. v. Fitch*, No. 1:24-cv-00160 [Dkt. #21] (“*PhRMA*”), and the additional grounds explained herein, this Court should deny Plaintiffs’ (sometimes collectively referred to as “AbbVie”) motion for preliminary injunction [Dkt. #8], which seeks to halt important provisions of 2024 Miss. H.B. 728 (“the Mississippi Law”) that protect Mississippi’s poorest citizens from the recent restrictions imposed by pharmaceutical giants.

Unlike Plaintiffs, at least nine other pharmaceutical companies have announced that they will comply with the Mississippi Law and deliver 340B drugs to an unlimited number of contract

pharmacies. Def. Ex. G, ¶ 5. Contrary to Plaintiffs’ unsupported allegations, the Mississippi Law does not create a risk of rampant fraud or diversion because adequate controls and federal oversight are already in place to ensure that 340B drugs are only dispensed to 340B qualified patients. The Mississippi Law is not an “arbitrage scheme” designed to divert 340B savings to commercial pharmacies. It is not preempted by federal law, nor does it effect an unconstitutional taking of private property. Rather, the Mississippi Law is quintessential state healthcare regulation designed to promote access to care for needy Mississippians. *Novartis* at 14 (“House Bill 728 plainly falls under the umbrella of a health and safety regulation”); *PhRMA* at 21 (“H.B[.] 728 aims to promote the health and welfare of [Mississippi’s] citizens”).

Exploiting a loophole in the federal 340B drug program—a program intended to benefit the needy—Plaintiffs in March 2023 began imposing their will on Mississippi medical providers and pharmacies, refusing to ship medications at federally mandated discounts to the very pharmacies that dispense those medications to underserved patients. Mississippi acted to close this loophole in a manner that the Eighth Circuit Court of Appeals recently held is constitutional. Plaintiffs disagree, claim the law is preempted and otherwise unconstitutional, and seek immediate relief on that basis. But Plaintiffs’ claims fail on the merits, and Plaintiffs flunk all remaining preliminary injunction requirements. Granting Plaintiffs relief would cause irreparable harm to the people of Mississippi by exacerbating the very public health problem that the challenged law seeks to address.

To start, Plaintiffs cannot be granted a preliminary injunction because all of their claims fail on the merits. As explained by this Court in its opinions issued in the companion *Novartis* and *PhRMA* cases, the presumption against preemption is effective here, and neither conflict preemption nor field preemption applies. *Novartis* at 13-23; *PhRMA* at 17-31. *See also Pharm.*

Research & Mfrs. of Am. v. McClain, 95 F.4th 1136, 1143-46 (8th Cir. 2024), *reh'g and reh'g en banc denied*, 2024 WL 1919676 (8th Cir. May 2, 2024). Plaintiffs' "takings" claims fare no better. Their state-law takings claim is barred by the Eleventh Amendment. Their federal "takings" claim fails because there has been no taking of private property. Plaintiffs voluntarily participate in the 340B program and must accordingly abide by H.B 728's state-law requirement that they not discriminate against 340B entities that use contract pharmacies to dispense 340B drugs to their patients. Even if Plaintiffs' withdrawal from Medicare and Medicaid would cause them significant financial loss, such economic hardship does not support a takings claim.

In sum, Plaintiffs cannot carry their heavy burden to overcome the well-settled presumption against federal preemption. Nor can they show a substantial likelihood of success on their federal or state-law takings claims. The Court's inquiry should end there, and Plaintiffs' motion should be denied on that basis alone.

Plaintiffs nevertheless flunk the remaining preliminary injunction factors. Critically, Plaintiffs have not shown irreparable harm. That at least nine pharmaceutical companies have announced that they will comply with the Mississippi Law undercuts any notion that Plaintiffs are irreparably harmed by the Mississippi Law. Further, Plaintiffs have not presented requisite evidence of "compliance costs" they will allegedly incur because of the Mississippi Law or proof that such costs are more than *de minimis*. To the extent Plaintiffs separately allege that compliance with the Mississippi Law will result in unrecoverable financial losses, they fail to make the requisite showing that the Mississippi Law threatens their very existence. In fact, with annual net revenues of \$54.3 billion, Plaintiffs face no significant threat at all.

Unquestionably, a preliminary injunction would disserve the public interest. Blocking the relief provided by the Mississippi Law will mean that covered providers from the State's largest

hospital to community hospitals to community health centers will continue to suffer significant shortfalls in 340B savings. That has a real-world impact on patient care in this State—a worsening reduction in healthcare services that will leave the State’s poorest citizens increasingly vulnerable to premature death and disease. A preliminary injunction would elevate Plaintiffs’ interest in bolstering their astronomical profits over the medical needs of poor Mississippians while this litigation is pending. It would also decrease access to 340B drugs for 340B qualified patients who are either too sick or who lack adequate transportation to travel to the sole pharmacy currently allowed by Plaintiffs. That cannot be in the public interest.

For these reasons and those set forth below, Plaintiffs fail to make the requisite showing for a preliminary injunction, and their motion should be denied.

BACKGROUND

To avoid redundancy, Defendant adopts and incorporates by reference the legal and factual summary set forth at pages 4-10 of the *Memorandum of Authorities in Support of Defendant Attorney General Lynn Fitch’s Response in Opposition to Plaintiff’s Motion for Preliminary Injunction* [Dkt. #12] filed in *Novartis Pharm. Corp. v. Fitch*, Civil Action No. 1:24-cv-00164-HSO-BWR (“the *Novartis* case”). Defendant submits the following additional factual background.

A. At least nine pharmaceutical companies have announced that they will voluntarily comply with the Mississippi Law.

Since the companion *Novartis* and *PhRMA* cases were filed, at least nine pharmaceutical companies (Amgen, Biogen, Boehringer Ingelheim, GSK, Merck, Organon, Pfizer, UCB, and Vertex) have announced that they will voluntarily comply with the Mississippi Law. Def. Ex. G, ¶ 5 and Ex. 1.

B. Plaintiffs incorrectly describe the purpose of the 340B program.

The 340B program’s purpose is not limited to ensuring that patients get access to discounted drugs. Even the authority that Plaintiffs cite does not support the proposition that “[t]he 340B program aims to help uninsured, low-income patients by providing them with better access to prescription medications at deeply discounted prices.” Dkt. #9 at 2. Rather, the 340B program is “a statutory scheme designed to reduce pharmaceutical costs *for safety-net medical providers* and the indigent populations they serve.” Connor J. Baer, *Drugs for the Indigent: A Proposal to Revise the 340B Drug Pricing Program*, Note, 57 WM. & MARY L. REV. 637, 638 (2015) (emphasis added) (footnote omitted). *See also id.* at 641 (“Congress enacted the 340B drug discount program . . . to help *certain safety-net medical service providers* ‘stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.’”) (emphasis added) (quoting H.R. Rep. No. 102-384(II), at 12 (1992)).

C. The Mississippi Law is not a pricing statute; it is an access-to-care statute.

In the midst of severe healthcare challenges and shortages in Mississippi, the 2024 Mississippi Legislature, with bipartisan support, enacted several critically important bills designed to maintain and hopefully improve access to care in Mississippi.¹ Relevant here, H.B. 728 was enacted to address discrimination against hospitals and other covered providers (“Covered Entities”) participating in the federal 340B program, to include providing protections for those Covered Entities that use contract pharmacies to dispense 340B drugs to qualifying patients.

¹ H.B. 539 was enacted to provide that qualifying pregnant women will be deemed presumptively eligible for Medicaid prenatal care for up to 60 days. H.B. 1376 establishes qualified residential treatment programs as alternative placements for children and youth who are in the custody of the Department of Child Protection Services. S.B. 2140, entitled the “Mississippi Prior Authorization Reform Act,” addresses prior authorization abuses by insurance companies and other payors. H.B. 1410 provides that an out-of-state health plan must reimburse providers in Mississippi at the same reimbursement rate for providers in the state of issuance.

H.B. 728 promotes access to healthcare in four important ways. First, Section 3 prohibits certain discriminatory acts that discourage participation in the 340B program and thus threaten access to 340B drugs by qualifying patients. Generally, Section 3 requires health insurance issuers and pharmacy benefit managers to treat Covered Entities no worse than they treat non-340B healthcare providers.

Second, Section 4, which prohibits discrimination based on the use of 340B contract pharmacies, enables 340B entities to provide medications to needy Mississippians across a wider geographic area than is currently permitted under many pharmaceutical companies' recently adopted restrictions. Many 340B hospitals and clinics serve patients who live far from the provider or the sole contract pharmacy currently allowed by Plaintiffs, and who lack adequate transportation to obtain needed medicines in a timely fashion. Def. Ex. G, ¶ 4A. Geographic access to 340B drugs is even more challenging for patients needing specialty pharmaceuticals, who are generally less mobile and can only obtain specialty medications through specialty pharmacies. Without access to their 340B drugs through contract pharmacies, these patients face delays or even denials of critical medications. *Id.*

Third, by eliminating obstacles to the use of contract pharmacies, the Mississippi Law restores 340B savings that 340B hospitals and clinics use to provide care to needy Mississippians who are unable to pay for their care. Without these protections, 340B providers will have no choice but to cut vital services.

Fourth, by allowing greater use of contract pharmacies, the Mississippi Law allows Covered Entities to increase the number of patients who receive direct drug care benefits from the 340B program. Contrary to Plaintiffs' unsupported allegations, Mississippi Covered Entities in many instances pass on 340B savings to qualifying patients in the form of cash savings cards to be

used when purchasing 340B drugs. *See* Def. Ex. D ¶ 10; Ex. F ¶ 7; Ex. G ¶ 4A. Thus, properly understood, the Mississippi Law fulfills an important healthcare need, falls clearly within the State’s traditional authority to regulate healthcare for the benefit of its citizens, *Novartis* at 14, *PhRMA* at 21, and in no way conflicts with the federal 340B statute.

D. Mississippi Covered Entities use 340B savings to fund much-needed patient services.

Plaintiffs’ allegation that Mississippi Covered Entities create an “arbitrage scheme” is contrary to the competent record evidence. Mississippi’s 340B hospitals and clinics use the 340B benefit to fund much-needed patient services they otherwise could not afford to offer. Though not required to do so, many Mississippi Covered Entities pass on the 340B discount directly to their patients. Def. Ex. D ¶ 10; Ex. F ¶ 7; Ex. G ¶ 4A.

Unlike Plaintiffs—which collectively generated \$4.86 billion in profits in 2023, Def. Ex. C, at 56—the evidence shows that Mississippi Covered Entities typically operate on razor-thin (and often negative) margins.² The 340B benefit they receive, including through the use of contract pharmacies, is a lifeline that Congress *intended* would help them “reach[] more eligible patients and provid[e] more comprehensive services.” H.R. Rep. No. 102-384(II), at 12 (1992). That is precisely what Mississippi’s 340B hospitals and clinics are doing.

² *See* AHA, *Setting the Record Straight on 340B: Fact vs. Fiction* 2 (Mar. 2021), <https://www.aha.org/system/files/2018-02/340BFactvsFiction.pdf>; Allen Dobson et al., *The Role of 340B Hospitals in Serving Medicaid and Low-income Medicare Patients* 12–13 (July 10, 2020), https://www.340bhealth.org/files/340B_and_Medicaid_and_Low_Income_Medicare_Patients_Report_7.10.2020_FINAL_.pdf.

E. The “replenishment model” disparaged by Plaintiffs is a commercially reasonable method of managing inventory and promotes compliance with 340B requirements.

The replenishment method of acquiring and managing 340B inventories is not the sinister scheme portrayed by Plaintiffs. In fact, it is a commercially reasonable method of acquiring 340B drugs and managing inventory to prevent diversion to non-340B patients. It is not, as Plaintiffs suggest, used to line the pockets of large commercial pharmacies.

When a 340B covered entity uses a contract pharmacy, the Covered Entity (not the pharmacy) orders and pays for the drugs, which are shipped directly to the pharmacy to be dispensed (or to replenish drugs that have been dispensed) to the 340B-qualified patients of the Covered Entity. *See Sanofi Aventis U.S. LLC v. HHS*, 58 F.4th 696, 700 (3d Cir. 2023) (“Covered entities using contract pharmacies would still order and pay for the drugs, but they would be shipped directly to the pharmacies.”). *See* Def. Ex. G ¶ 4B; Dkt. #8-2, ¶¶ 4–13. The Covered Entity pays a fee to the pharmacy—as it would for any drugs the pharmacy dispenses on the provider’s behalf—which is generally a flat fee ranging between \$6 and \$15 per prescription, though it can be as low as \$0 and occasionally higher for more expensive drugs; a fee based on percentage of revenue; or a combination.³

The replenishment method does not render the dispensing of 340B drugs to 340B patients “a fiction,” and the contract pharmacy does not simply “later determine[] how much of its stock it thinks it has dispensed to customers who might have at one time been patients of a covered entity.” Dkt. #9 at 17-18 (Brief 16-17). Whether the patient is 340B qualified is determined by the Covered Entity or *its* third-party administrator. Def. Ex. G ¶ 4C. As the Pedley Declaration submitted by

³ *Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement*, GAO-18-480, Report to Congressional Requesters 24–27 (June 2018), <https://www.gao.gov/assets/gao-18-480.pdf>.

AbbVie itself confirms, “340B-tailored software programs” ensure that the 340B discount attaches *only* to drugs dispensed to 340B patients. Dkt. #8-2 at ¶ 6. HHS performs regular audits of these sales, and “the covered entity has to provide auditable records that show each dispense that was deemed 340B-eligible is actually tied to a 340B-eligible patient.” *Id.* Importantly, the Supreme Court and the Federal Trade Commission have endorsed similar accounting systems as an appropriate way to distinguish drugs that qualify for a discount from those that do not.⁴

Plaintiffs’ contention that “poor patients do not get cheap drugs—commercial pharmacies do,” Dkt. #9 at 6 (Brief 5), does not comport with reality. First, the sole evidentiary basis for this accusation is the declaration of Edward Scheidler, Dkt. #8-1, whose sweeping allegations are both speculative and untethered to 340B practices in Mississippi. Second, Scheidler’s declaration is directly contradicted by AbbVie’s Pedley Declaration, which clearly explains how 340B hospitals and clinics properly use contract pharmacies and how HRSA ensures the integrity of their use through regular audits. *See* Dkt. #8-2.

Nevertheless, to avoid any lingering doubt, Defendant submits the Declaration of Trenton DeLand Lott, Pharm. D., A.C.E., who has personal knowledge of 340B practices within Mississippi. Def. Ex. G. Mr. Lott’s declaration reviews each of Mr. Scheidler’s inaccurate statements, clearly rebutting each one. *Id.* at ¶ 4, B. Mr. Lott further explains that “[t]he covered entities themselves set the criteria for determining if a patient is 340B qualified, and the covered entity (not the contract pharmacy) contracts with the third-party administrator (TPA).” *Id.* at ¶ 4, C. “[N]eeded patients without insurance or governmental coverage do receive the benefit of the

⁴ *See Abbott Labs. v. Portland Retail Druggist Ass’n, Inc.*, 425 U.S. 1, 20 n.11 (1976); Federal Trade Commission, University of Michigan Advisory Opinion 1 (Apr. 9, 2010), <https://www.ftc.gov/sites/default/files/documents/advisory-opinions/university-michigan/100409univmichiganopinion.pdf>.

340B discount. For qualified self-pay patients, the contract pharmacy receives only a dispensing fee. For qualified patients with coverage, the payor pays the agreed upon price or the price set by the applicable governmental agency (e.g., Medicare or Medicaid). The contract pharmacy is paid a reasonable fee for dispensing the 340B drugs but bears all of the cost of operating the pharmacy. The 340B covered entity retains the balance of the 340B discount, which is used to maintain or increase services available to needy Mississippians.” *Id.* at ¶ 4, D.

Plaintiffs’ unsubstantiated tale of abuses is further refuted by recent data for fiscal years 2019 through 2022, when the federal government conducted more than 600 audits of 340B hospitals with almost 95 percent of those audits identifying no instances of diversion related to contract pharmacies.⁵ And to the extent Plaintiffs are concerned about diversion (or duplicate discounts), the 340B statute already provides for audits and enforcement. *See* 42 U.S.C. § 256b.

In short, Plaintiffs’ purported facts offered in support of maintaining their restrictions on contract pharmacies are inaccurate and provide no basis for granting a preliminary injunction.

STANDARD FOR INJUNCTIVE RELIEF

Motions for preliminary injunction are governed by Rule 65, *Federal Rules of Civil Procedure*. A party seeking a preliminary injunction must demonstrate each of the following: (1) a substantial likelihood of success on the merits; (2) a substantial threat of irreparable injury if the injunction is not issued; (3) that the threatened injury if the injunction is denied outweighs any harm that will result if the injunction is granted; and (4) that the grant of an injunction will not disserve the public interest. *Big Tyme Investments, L.L.C. v. Edwards*, 985 F.3d 456, 463-64 (5th

⁵ *See* Health Res. & Servs. Admin., *Program Integrity: FY19 Audit Results*, <https://www.hrsa.gov/opa/program-integrity/audit-results/fy-19-results>; *Program Integrity: FY20 Audit Results*, <https://www.hrsa.gov/opa/program-integrity/fy-20-audit-results>; *Program Integrity: FY21 Audit Results*, <https://www.hrsa.gov/opa/program-integrity/fy-21-audit-results>; *Program Integrity: FY22 Audit Results*, <https://www.hrsa.gov/opa/program-integrity/audit-results/fy-22-results>.

Cir. 2021). The third and fourth requirements, *viz.*, the balance of the equities and the public interest, merge and are considered together when the government is the opposing party. *Pacharne v. Dep't of Homeland Sec.*, 565 F. Supp. 3d 785, 802 (N.D. Miss. 2021).

The four above-listed “requirements are not balanced. Instead, each one must be met before the Court can provide relief.” *Pinkston v. Hall*, Civil Action No. 5:18-cv-103-MTP, 2020 WL 2529398, at *8 n.10 (S.D. Miss. May 18, 2020). The burden is on the party seeking injunctive relief to establish all four elements. *Carlisle v. Elite Trucking Servs., LLC*, Civil No. 1:16-CV-257-JCG, 2016 WL 9223832, at *1 (S.D. Miss. Nov. 4, 2016). If the moving party “fails to carry its burden on any one of the four elements . . . , the Court must deny the request for injunctive relief.” *Miller v. Miss. Res., LLC*, Civil Action No. 5:17-cv-41-DCB-MTP, 2017 WL 2772097, at *2 (S.D. Miss. June 26, 2017). “The decision to grant a preliminary injunction is to be treated as the exception rather than the rule.” *Miss. Power & Light Co. v. United Gas Pipe Line Co.*, 760 F.2d 618, 621 (5th Cir. 1985). “[A] federal judge sitting as chancellor is not mechanically obligated to grant an injunction for every violation of law.” *Weinberger v. Romero-Barcelo*, 456 U.S. 305, 313 (1982).

ARGUMENT

I. THE COURT SHOULD DENY PLAINTIFFS’ MOTION FOR PRELIMINARY INJUNCTION BECAUSE ALL OF THE GOVERNING FACTORS WEIGH AGAINST GRANTING PRELIMINARY INJUNCTIVE RELIEF.

A. Plaintiffs have failed to establish a substantial likelihood of success on the merits.

Plaintiffs seek a preliminary injunction predicated exclusively upon their preemption and federal and state “takings” claims. This Court carefully analyzed and rejected the plaintiffs’ preemption claims in *Novartis* and *PhRMA*. For the reasons this Court explained there, the Court

should likewise reject Plaintiffs’ preemption claims in this case. For completeness, Defendant submits the following arguments and authorities in opposition to both preemption and takings.

“[T]he absence of likelihood of success on the merits is sufficient to make the district court’s grant of a preliminary injunction improvident as a matter of law.” *Lake Charles Diesel, Inc. v. Gen. Motors Corp.*, 328 F.3d 192, 203 (5th Cir. 2003). “If the party requesting a preliminary injunction *cannot* show a substantial likelihood of success on the merits, the injunction should be denied and there is no need for the court to address the other requirements for a preliminary injunction.” *Edwards*, 985 F.3d at 464 (internal quotation marks omitted) (*italics in original*). *See also Stevens v. St. Tammany Parish Gov’t*, 17 F.4th 563, 576 (5th Cir. 2021) (*same*).

1. In challenging the Mississippi Law on constitutional grounds, Plaintiffs face a heavy burden—one made heavier by a presumption against federal preemption.

“A statute enacted by the Mississippi Legislature is presumed constitutional.” *White v. Wexford Health Sources, Inc.*, Civil Action No. 2:09-CV-00161-GHD-JMV, 2012 WL 3000645, at *2 (N.D. Miss. July 23, 2012). “Accordingly, a party challenging the constitutionality of a statute must prove his case by showing the unconstitutionality of the statute beyond a reasonable doubt.” *Id.* *See also Exxon Corp. v. Bd. of Educ. of Lamar County*, 849 F. Supp. 479, 489 (S.D. Miss. 1994) (*same*).

In the specific context of preemption, “[f]ederal preemption of state law flows from the Supremacy Clause.” *Deanda v. Becerra*, 96 F.4th 750, 760 (5th Cir. 2024). “In determining a federal statute’s preemptive reach, congressional purpose is ‘the ultimate touchstone.’” *United Motorcoach Ass’n, Inc. v. City of Austin*, 851 F.3d 489, 492 (5th Cir. 2017) (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996)). But “[t]he power to supplant state law is “an extraordinary power in a federalist system.”” *White Buffalo Ventures, LLC v. Univ. of Tex. at Austin*, 420 F.3d 366, 370 (5th Cir. 2005) (quoting *Gregory v. Ashcroft*, 501 U.S. 452, 460 (1991)). “Preemption

radically alters the balance of state and federal authority, so the Supreme Court has historically refused to impose that alteration interstitially. [Citation omitted.] The Court has expressed this principle as a *presumption against preemption of state law*.” *Id.* (emphasis added).

Accordingly, “[i]n all pre-emption cases,” *Wyeth v. Levine*, 555 U.S. 555, 565 (2009) (emphasis added), “[p]reemption analysis begins with the assumption that the historic police powers of the States [are] not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.” *Deanda*, 96 F.4th at 761 (internal quotation marks omitted). “This presumption against preemption is applicable to areas of law traditionally reserved to the states.” *Id.* (internal quotation marks omitted). “Congress did not intend to supersede the historic police powers of the states to protect the health and safety of their citizens.” *Elam v. Kansas City S. Ry. Co.*, 635 F.3d 796, 813 (5th Cir. 2011) (quoting *Medtronic*, 518 U.S. at 475) (internal quotation marks omitted). Thus, the “presumption against preemption applies to state or local regulation of matters of health and safety.” *Pennington v. Vistrion Corp.*, 876 F.2d 414, 417 (5th Cir. 1989) (citing *Hillsborough County v. Automated Med. Labs., Inc.*, 471 U.S. 707, 715 (1985)). There is a “presumption that [such] matters [are] not invalidated under the Supremacy Clause.” *Hillsborough County*, 471 U.S. at 715.

“Supremacy Clause analysis is classic ‘tie goes to the state’ jurisprudence.” *White Buffalo*, 420 F.3d at 370. “The party asserting federal preemption has the burden of persuasion.” *Elam*, 635 F.3d at 802. “Preemption is not lightly found,” and the party asserting it “bears a heavy burden of proof.” *Iberia Credit Bureau, Inc. v. Cingular Wireless*, 668 F. Supp. 2d 831, 837 (W.D. La. 2009) (citing *Wis. Pub. Intervenor v. Mortier*, 501 U.S. 597 (1991)).

2. The Mississippi Law is not preempted by the 340B Statute.

There are three types of federal preemption: (1) express preemption; (2) field preemption; and (3) conflict preemption. *Simmons v. Sabine River Auth. of La.*, 732 F.3d 469, 473 (5th Cir. 2013). Plaintiffs do not claim or argue express preemption because 42 U.S.C. § 256b (“the 340B Statute”) does not contain an express preemption provision.

Field Preemption. “Field preemption exists when (1) the scheme of federal regulation is sufficiently comprehensive to make reasonable the inference that Congress left *no room* for supplementary state regulation, or (2) where the field is one in which the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject.” *Aldridge v. Miss. Dep’t of Corr.*, 990 F.3d 868, 874 (5th Cir. 2021) (internal quotation marks omitted) (emphasis added). “When analyzing field preemption, ‘the relevant field should be defined narrowly.’” *United States v. Texas*, 97 F.4th 268, 278 (5th Cir. 2024) (quoting *City of El Cenizo, Tex. v. Texas*, 890 F.3d 164, 177 (5th Cir. 2018)).

“Field preemption of state law is disfavored.” *Nat’l Press Photographers Ass’n v. McCraw*, 90 F.4th 770, 796 (5th Cir. 2024). It “should not be inferred . . . simply because [a federal] agency’s regulations are comprehensive.” *See R.J. Reynolds Tobacco Co. v. Durham County, N.C.*, 479 U.S. 130, 149 (1986). Further, “where Congress has chosen to ‘occupy’ a field, but has not undertaken to regulate every aspect of that area, the states have the implied reservation of power to fill out the scheme.” *Chem. Specialties Mfrs.’ Ass’n, Inc. v. Clark*, 482 F.2d 325, 327 (5th Cir. 1973). *See also Smith v. Pingree*, 651 F.2d 1021, 1024 (5th Cir. 1981) (same).

In this case, the 340B Statute does not preempt the relevant field of *delivery* of 340B drugs to contract pharmacies, for distribution to the patient population such drugs are intended to benefit. The functional legislative purpose of the 340B Statute—according to its plain language—is to

regulate participating pharmaceutical manufacturers’ *pricing* and *discounting* of 340B drugs sold to Covered Entities. *See* 42 U.S.C. § 256b. Significantly, the 340B Statute does not regulate the acquisition, distribution, and/or dispensation of 340B drugs—that is, the *delivery* of 340B drugs to patients—via contract pharmacies or otherwise. It is 340B drug *delivery* to patients, via contract pharmacies, that the Mississippi Law regulates. For the following reasons, Congress has not occupied the relevant field.

First, “the 340B Program is not so pervasive . . . that Congress left no room for the States to supplement it.” *Pharm. Research & Mfrs. of Am. v. McClain*, 95 F.4th 1136, 1143 (8th Cir. 2024), *reh’g and reh’g en banc denied*, 2024 WL 1919676 (8th Cir. May 2, 2024) (internal quotation marks omitted) (ellipsis in original). “Pharmacies have always been an essential part of the 340B program. Yet, the text of 340B is silent about *delivery* of drugs to patients.” *Id.* (internal quotation marks omitted) (emphasis added). “Nowhere does Section 340B mention contract pharmacies,” and the 340B Statute, being “silent about delivery,” instead “directs its compliance provisions at covered entities, not contract pharmacies.” *Sanofi Aventis U.S. LLC v. U.S. Dep’t of Health & Human Servs.*, 58 F.4th 696, 703, 705 (3d Cir. 2023). *See also AstraZeneca Pharms. LP v. Becerra*, 543 F. Supp. 3d 47, 59 (D. Del. 2021) (“The [340B] statute is silent as to the role that contract pharmacies may play in connection with covered entities’ purchases of 340B drugs. Pharmacies are not mentioned anywhere in the statutory text.”); *Novartis Pharms. Corp. v. Johnson*, --- F.4th ---, 2024 WL 2279829, at *5 (D.C. Cir. May 21, 2024) (“Section 340B is . . . silent about delivery conditions”). “Congress’s decision not to legislate the issue of pharmacy distribution indicates that Section 340B is not intended to preempt the field.” *McClain*, 95 F.4th at 1143 (emphasis added).

Second, the field of 340B drug delivery cannot be said to be an area in which the federal interest is so dominant as to preclude enforcement of state laws bearing on the subject. This is because “the practice of pharmacy is an area traditionally left to state regulation.” *See id.* (quoting *Pharm. Care Mgmt. Ass’n v. Wehbi*, 18 F.4th 956, 972 (8th Cir. 2021)) (internal quotation marks omitted). “Indeed, when it comes to pharmaceuticals, the federal government has traditionally regarded state law as a complementary form of drug regulation and has long maintained that state law offers an additional, and important, layer of consumer protection that complements [federal] regulation.” *McClain*, 95 F.4th at 1143 (ultimately quoting *Wyeth*, 555 U.S. at 578-79) (internal quotation marks omitted) (alteration in original). Because “Congress was aware of the role of pharmacies and state pharmacy law in implementing 340B,” its “silence on pharmacies in the context of 340B indicates that Congress did not intend to preempt the field.” *Id.* at 1144.

Undeterred, Plaintiffs argue that field preemption applies because “Section 340B erects a comprehensive regulatory scheme governing an exclusively federal program.” Dkt. #9 at 14 (Brief 13). But merely “[i]nvoking some brooding federal interest . . . should never be enough to win preemption of a state law.” *Va. Uranium, Inc. v. Warren*, 587 U.S. 761, 767 (2019). As the Supreme Court has explained, “[t]he subjects of modern social and regulatory legislation often by their very nature require intricate and complex responses from the Congress, but without Congress necessarily intending its enactment as the exclusive means of meeting the problem.” *N.Y. State Dep’t of Soc. Servs. v. Dublino*, 413 U.S. 405, 415 (1973). Thus, the Supreme Court has rejected “the contention that pre-emption is to be inferred merely from the comprehensive character” of federal provisions. *Id.* *See also English v. Gen. Elec. Co.*, 496 U.S. 72, 87 (1990) (“Ordinarily, the mere existence of a federal regulatory or enforcement scheme, even one as detailed as § 210 [of the Energy Reorganization Act of 1974], does not by itself imply pre-emption of state

remedies.”). With the 340B program, “a detailed statutory scheme was both likely and appropriate, completely apart from any questions of pre-emptive intent.” *See Dublino*, 413 U.S. at 415.

Plaintiffs are also mistaken that “every detail of the 340B program is determined by federal law.” Dkt. #9 at 14 (Brief 13). *See Pharm. Research & Mfrs. of Am. v. McClain*, 645 F. Supp. 3d 890, 899 (E.D. Ark 2022), *aff’d*, 95 F.4th 1136 (8th Cir. 2024) (“[T]he 340B Program is silent on what role (if any) contract pharmacies play in its discount drug scheme Arkansas’s covered entities have filled in this gap through contract pharmacy arrangements. The 340B Program is not ‘so pervasive as to make reasonable the inference that Congress left no room for States’ to protect their specific drug distribution systems.”) (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). *See also Chinatown Neighborhood Ass’n v. Harris*, 794 F.3d 1136, 1143 (9th Cir. 2015); *Frank Bros., Inc. v. Wis. Dep’t of Transp.*, 409 F.3d 880, 891 (7th Cir. 2005). *Cf. F.D.I.C. v. McFarland*, 243 F.3d 876, 888 (5th Cir. 2001) (acknowledging “comprehensive and detailed [federal] statutory scheme” but emphasizing that “‘matters left unaddressed in such a scheme are presumably left subject to the disposition provided by state law’”) (quoting *O’Melveny & Myers v. FDIC*, 512 U.S. 79, 85 (1994)).

It is likewise no help to Plaintiffs that some federal courts have interpreted the 340B Statute as not precluding manufacturers from “interfering” with contract pharmacies by refusing to distribute 340B drugs to multiple pharmacies under contract with a single Covered Entity. That is because no court has held that the 340B Statute, which governs pricing and discounting of certain drugs, contemplates or requires such interference—only that such interference is not prohibited by federal law. Significantly, no court has ever held that a State cannot exercise its “implied reservation of power to fill out the scheme,” see *Clark*, 482 F.2d at 327, by regulating in the area

of 340B drug *delivery* to contract pharmacies. For all these reasons, the Mississippi Law is not preempted by the 340B Statute via field preemption.

Conflict Preemption. “[C]onflict preemption begins with the presumption ‘that Congress did not intend to displace state law.’” *Young Conservatives of Tex. Found. v. Smatresk*, 73 F.4th 304, 313 (5th Cir. 2023) (quoting *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981)). “For a state law to be conflict preempted, ‘a high threshold must be met.’” *Barrosse v. Huntington Ingalls, Inc.*, 70 F.4th 315, 320 (5th Cir. 2023) (quoting *Chamber of Commerce v. Whiting*, 563 U.S. 582, 607 (2011)). Thus, “[c]ourts may not conduct ‘a freewheeling judicial inquiry into whether a state statute is in tension with federal objectives [because] such an endeavor would undercut the principle that it is Congress rather than the courts that pre-empt state law.’” *Id.* (quoting *Whiting*, 563 U.S. at 607) (second alteration in original).

Given these guardrails, conflict preemption may only be found if (1) compliance with both state law and federal law is impossible (“impossibility preemption”); or (2) a state law stands as an unacceptable obstacle to the accomplishment and execution of the full purposes and objectives of Congress (“obstacle preemption”). *Id.* at 320. Plaintiffs do not argue “impossibility preemption,”⁶ and the Mississippi Law does not implicate “obstacle preemption.”

As to the latter, Congress enacted the 340B Statute in response to the “substantial price increases” that pharmaceutical manufacturers imposed on outpatient drugs sold to the VA, federally funded clinics, and public hospitals in an attempt by manufacturers to limit their exposure to Medicaid rebates. *See Genesis Health Care, Inc. v. Becerra*, Civil Action No. 4:19-cv-01531-RBH, 2023 WL 7549156, at *1 (D.S.C. Nov. 3, 2023). “By providing ‘covered entities’ access to

⁶ To the extent Plaintiffs do in fact contend that “impossibility preemption” applies here, Defendant adopts and incorporates by reference her arguments in opposition to “impossibility preemption” set forth at pages 19-20 of the *Memorandum of Authorities in Support of Defendant Attorney General Lynn Fitch’s Response in Opposition to Plaintiff’s Motion for Preliminary Injunction* [Dkt. #12] filed in the *Novartis* case.

price reductions, the 340B program would enable [covered entities] to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.” *Id.* (alteration in original) (internal quotation marks omitted). This allows Covered Entities “to provide more services to a larger population of under-served patients.” *Id.* The 340B Statute thus serves the “public purposes” of “assist[ing] uninsured patients in affording costly medications and under-resourced providers in serving more people.” *Sanofi-Aventis U.S., LLC v. U.S. Dep’t of Health & Human Servs.*, 570 F. Supp. 3d 129, 209 (D.N.J. 2021), *aff’d in part, rev’d in part on other grounds*, 58 F.4th 696 (3d Cir. 2023).

The Mississippi Law does not create any obstacle to accomplishing the legislative purpose of the 340B Statute. Again, the evidence shows that, to date, at least nine non-party drug companies have announced that they will voluntarily comply with the Mississippi Law—meaning they evidently do not regard the Mississippi Law as an obstacle to their compliance with the 340B Statute. Further, by supporting Covered Entities’ engagement of multiple contract pharmacies to dispense 340B drugs to qualifying patients, the Mississippi Law in fact “assists in fulfilling the purpose of 340B” to stretch scarce resources to provide care for needy Mississippians. *See McClain*, 95 F.4th at 1145. Thus, “obstacle preemption” is likewise inapplicable here.

Plaintiffs fail to show that any provision of the Mississippi Law *actually conflicts* with the 340B Statute. There is no federal statutory *prohibition* on Covered Entities’ use of contract pharmacies, nor is there any federal *limitation* on the number of pharmacies with which a Covered Entity may contract. Plaintiffs have not shown a direct conflict, much less a conflict sufficient to overcome the presumption against conflict preemption.

Likewise, the different penalties imposed by the Mississippi Law on pharmaceutical manufacturers that violate *the Mississippi Law* do not create a conflict with the penalties that

federal law provides for diversion, duplicate discounts, or overcharging in violation of the 340B Statute. The Mississippi Law’s penalties “are aimed at activity that falls outside the purview of 340B.” *See McClain*, 95 F.4th at 1145. Mississippi “is simply deterring pharmaceutical manufacturers from interfering with a covered entity’s contract pharmacy arrangements. There is no obstacle for pharmaceutical manufacturers to comply with both [the Mississippi Law] and Section 340B.” *See id.*

Plaintiffs get no help from *Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110 (2011). The sole issue before the Court in *Astra* was whether Covered Entities could sue manufacturers “as third-party beneficiaries of the PPAs to which the manufacturers subscribed.” *Astra*, 563 U.S. at 113. The Court’s narrow holding in *Astra* was that “suits by 340B entities to enforce ceiling-price contracts running between drug manufacturers and the Secretary of HHS are incompatible with the statutory regime.” *Id.* The Court’s holding rested upon its determination that “suits to enforce § 340B and suits to enforce PPAs are in substance one and the same,” and since “Congress authorized no private right of action” as to the former, no such action could lie as to the latter. *See id.* at 113-14. The issue of federal preemption was not before the Court in *Astra*. In fact, the *Astra* Court expressly declined to address preemption. *See id.* at 120 n.5 (“We take no position on this issue.”). Plaintiffs’ reliance on *Astra* is accordingly misplaced.⁷

Nothing in *Astra* displaces the well-settled principle that “the mere existence of a federal regulatory or enforcement scheme . . . does not by itself imply preemption of state remedies.” *English*, 496 U.S. at 87. As noted *supra*, “[t]he subjects of modern social and regulatory legislation

⁷ At least one federal district court rejected *Astra* as supporting federal preemption in the 340B context of state regulation of contract pharmacy restrictions. *See Pharm. Research & Mfrs. of Am. v. McClain*, 645 F. Sup. 3d 890, 899 (E.D. Ark. 2022), *aff’d*, 95 F.4th 1136 (8th Cir. 2024), *reh’g and reh’g en banc denied*, 2024 WL 1919676 (8th Cir. May 2, 2024) (“I am not convinced that the Supreme Court’s narrow holding concerning third-party lawsuits in *Astra* makes the 340B Program a solely federal scheme immune from any type of state regulation.”).

often by their very nature require intricate and complex responses from the Congress, but without Congress necessarily intending its enactment as the exclusive means of meeting the problem.” *Dublino*, 413 U.S. at 415. Accordingly, “[t]o infer preemption whenever an agency deals with a problem comprehensively is virtually tantamount to saying that whenever a federal agency decides to step into a field, its regulations will be exclusive. Such a rule, of course, would be inconsistent with the federal-state balance embodied in our Supremacy Clause jurisprudence.” *Hillsborough County*, 471 U.S. at 717.

3. Plaintiffs fail to establish the elements of a “takings” claim under the Fifth Amendment to the U.S. Constitution or under the Mississippi Constitution.

Plaintiffs’ “takings” claim under the Mississippi Constitution is barred by the Eleventh Amendment. And Plaintiffs’ “takings” claims under both the Mississippi Constitution and the Fifth Amendment to the U.S. Constitution fail because Plaintiffs cannot establish an unconstitutional taking of private property.

a. The Eleventh Amendment prohibits federal jurisdiction over Plaintiffs’ state-law “takings” claim.

Plaintiffs’ claim of a “taking” under Article III, Section 17, of the Mississippi Constitution is clearly barred by the Eleventh Amendment. *See Pennhurst State Sch. & Hosp. v. Halderman*, 465 U.S. 89, 106 (1984). In *Pennhurst*, the Supreme Court held that under the Eleventh Amendment “federal courts lack[] jurisdiction to enjoin . . . state institutions and state officials on the basis of [a] state law. *Id.* at 124-25. A State’s Eleventh Amendment immunity is necessarily implicated when a federal court “instructs state officials on how to conform their conduct to state law,” because “[s]uch a result conflicts directly with the principles of federalism that underlie the Eleventh Amendment.” *Id.* at 106.

Citing the Supreme Court’s holding in *Pennhurst*, the Fifth Circuit has repeatedly reaffirmed that “the Eleventh Amendment prohibits federal courts from enjoining state [officials] to follow state law.” *See, e.g., Valentine v. Collier*, 956 F.3d 797, 802 (5th Cir. 2020). *See also Fairley v. Louisiana*, 254 Fed. App’x 275, 277 (5th Cir. 2007) (reaffirming that “[f]ederal courts simply lack the power to order state officials to conform their conduct to state law”) (citing *Pennhurst*); *Doe v. Harrell*, 841 Fed. App’x 663, 669 (5th Cir. 2021) (same) (quoting *Pennhurst*).

Plaintiffs’ pendent state law takings claim seeks to enjoin the Mississippi Attorney General to follow their interpretation of MISS. CONST. art. III, § 17. Even if Plaintiffs’ unsupported interpretation were correct—which it is not—this is a prohibited attempt to have a federal court dictate Mississippi’s compliance with its own law. Accordingly, this Court lacks jurisdiction over this claim under the Eleventh Amendment.

b. Plaintiffs’ federal and state-law takings claims fail on the merits.

The first step in any takings analysis is to identify a private property interest. *See Guilbeau v. Parish of St. Landry*, Civil Action No. 06-0185, 2008 WL 4948836, at *10 (W.D. La. Nov. 19, 2008) (“Indeed, ‘[t]he sine qua non of a constitutional taking is a loss occasioned by an intrusion, interference or encroachment of some degree *upon the private property owner’s rights in his property.*’”) (emphasis in original) (quoting *Fla. E. Coast Props., Inc. v. Metro. Dade County*, 572 F.2d 1108, 1111 (5th Cir. 1978)). But a taking does not occur when a private property owner voluntarily participates in a regulated activity. *See Baker County Med. Servs., Inc. v. U.S. Atty. Gen.*, 763 F.3d 1274, 1276 (11th Cir. 2014) (collecting cases). Here, as determined in numerous federal court decisions, Plaintiffs’ decision to participate in the 340B program by participating in Medicaid and Medicare is *voluntary*. It is their choice to participate in these three programs, and the voluntary nature of their participation forecloses any “takings” claim.

In recent years, numerous Fifth Amendment challenges have been made to regulatory requirements of federal and state healthcare programs, including requirements on pharmaceutical companies that participate in the 340B program to use contract pharmacies. In every case of which Defendant is aware, the court held that no unconstitutional taking occurred because the pharmaceutical company or other challenger had a choice as to whether to participate in the government program. *See Baker*, 763 F.3d at 1276; *Minn. Ass’n of Health Care Facilities, Inc. v. Minn. Dep’t of Pub. Welfare*, 742 F.2d 442, 446 (8th Cir. 1984); *Garelick v. Sullivan*, 987 F.2d 913, 916 (2d Cir. 1993), *cert. denied*, 510 U.S. 821 (1993); *Burditt v. U.S. Dep’t of Health & Human Servs.*, 934 F.2d 1362, 1376 (5th Cir. 1991); *Whitney v. Heckler*, 780 F.2d 963, 972-74 (11th Cir. 1986); *St. Francis Hosp. Ctr. v. Heckler*, 714 F.2d 872, 875 (7th Cir. 1983); *Eli Lilly & Co. v. U.S. Dep’t of Health & Human Servs.*, No. 1:21-cv-00081-SEB-MJD, 2021 WL 5039566, at *21 (S.D. Ind. Oct. 29, 2021); *Sanofi-Aventis U.S., LLC v. U.S. Dep’t of Health & Human Servs.*, 570 F. Supp. 3d 129, 207-10 (D.N.J. 2021), *rev’d on other grounds*, 58 F.4th 696 (3d Cir. 2023).

In *Eli Lilly & Co.*, Eli Lilly argued that the Department of Health and Human Services’ implementation of the 340B program effected a taking “by forcing Lilly to transfer its drugs to contract pharmacies solely to serve those entities’ private interests, and that, by requiring Lilly to succumb to a private taking of property to obtain coverage of its drugs under federal health-insurance programs,” the program imposed “an unconstitutional condition on a valuable government benefit.” *Eli Lilly & Co.*, 2021 WL 5039566 at *21. The Southern District of Indiana disagreed. The plaintiff’s voluntary participation in the 340B Drug Program “forecloses the possibility that the statute could result in an imposed taking of private property which would give rise to the constitutional right of just compensation.” *Id.* (quoting *S.E. Ark. Hospice, Inc. v. Burwell*, 815 F.3d 448, 450 (8th Cir. 2016)) (internal quotation marks omitted). Although

withdrawing from 340B—and therefore, necessarily, Medicaid and Medicare Part B—would “result in a significant financial impact for” Eli Lilly, such realities were insufficient to find legal compulsion for the purposes of the court’s takings analysis. *Id.*

In *Sanofi-Aventis*, the New Jersey district court rejected identical claims on multiple grounds, including that “[the drug manufacturer] voluntarily joined the 340B program with full knowledge of the discount scheme it effected” and “[it] has not lost all ‘economically viable use’ associated with 340B-priced drugs.” *Sanofi-Aventis*, 570 F. Supp. 3d at 207-10.

In *Minnesota Association of Health Care Facilities*, 742 F.2d at 442, the Eighth Circuit addressed a state statute, which like the Mississippi Law established requirements for healthcare entities participating in a federal program. According to that court, a Minnesota statute requiring nursing homes participating in Medicaid to accept limits on rates charged to certain residents did not constitute a taking under the Fifth Amendment. *Id.* at 446. The court explained that “[d]espite the strong financial inducement to participate in Medicaid, a nursing home’s decision to do so is nonetheless *voluntary*,” which “forecloses the possibility that the statute could result in an imposed taking of private property which would give rise to the constitutional right of just compensation.” *Id.* (emphasis added).

In *Burditt v. U.S. Dep’t. of Health & Human Servs.*, 934 F.2d 1362 (5th Cir. 1991), the Fifth Circuit reached the same conclusion in the context of the Emergency Medical Treatment and Active Labor Act (EMTALA), 42 U.S.C. § 1395dd. There, a physician argued that EMTALA’s requirement that he provide emergency medical care to patients presenting to the hospital emergency room constituted a taking without just compensation in violation of the Fifth Amendment. Rejecting this claim on multiple grounds, the Fifth Circuit reaffirmed that “[g]overnmental regulation that affects a group’s property interests ‘does not constitute a taking

of property where the regulated group is not required to participate in the regulated industry.” *Burditt*, 934 F.2d at 1376 (quoting *Whitney*, 780 F.2d at 972).

Plaintiffs’ takings claim also fails the test for a *per se* taking and the three-part test that the Supreme Court set out in *Penn Central Transp. Co. v. New York City*, 438 U.S. 104, 124 (1978). It fails the *per se* test because what is involved here is a discount, not a full taking—*i.e.*, there is still economically viable use of Plaintiffs’ drugs under the Mississippi Law. *See Sanofi-Aventis*, 570 F. Supp. 3d at 207 (citing *Murr v. Wisconsin*, 137 S. Ct. 1933, 1937 (2017)). The claim also fails the *Penn Central* regulatory takings analysis. First, the sale of 340B drugs to Covered Entities using contract pharmacies still reaps a profit, and even if it did not, 340B sales in total represent only about five percent of the prescription drug market and fourteen percent of the branded drug market. *Sanofi-Aventis*, 570 F. Supp. 3d at 208. Second, Plaintiffs do not have a reasonable investment-backed expectation because of the power of the State to regulate in the public interest, which makes it unreasonable for Plaintiffs to expect to be free from regulation under the 340B program. *See id.* at 209. Finally, based on the character of the government action, there is an obvious connection to multiple public interests, which weighs against deeming the action a “taking.” *Id.*

Like the plaintiffs in the cases discussed above, Plaintiffs here have not suffered an unconstitutional taking. Their desire to continue participating in Medicare and Medicaid does not leave them with no choice but to participate in the 340B program, even though a significant portion of Plaintiffs’ business may come from Medicare and Medicaid. They are free to opt out. Thus, Plaintiffs have failed to show a substantial likelihood of success on their federal or state takings claims.

B. Plaintiffs fail to make the requisite showing of irreparable harm.

Irreparable harm is a separate preliminary injunction requirement. Plaintiffs cannot satisfy it simply by pointing back to a showing on the merits requirement for injunctive relief. *See White v. Calrucci*, 862 F.2d 1209, 1211 (5th Cir. 1989) (“Without question, the irreparable harm element must be satisfied by independent proof, or no injunction may issue.”).

As noted above, Defendant has submitted recent announcements from nine non-party drug companies stating that they intend to comply with the Mississippi Law and not restrict the number of contract pharmacies that a 340B Covered Entity may use. Def. Ex. G, ¶ 5 and Ex. 1. This is strong evidence that the Mississippi Law does not irreparably harm drug companies that sell 340B drugs to Covered Entities in Mississippi.

Faced with these hurdles, Plaintiffs submit only two arguments (but no objective evidence) in support of their irreparable harm element: (1) that they “would be exposed to *state* regulation—including the risk of criminal liability—as a condition of participating in the *federal* 340B program and would risk violating H.B. 728 simply by performing its federally mandated functions,” (emphasis in original) and (2) that if H.B. 728 were enforced against Plaintiffs, they would be “subject to an ongoing unconstitutional taking of private property.” Dkt. #9 at 23 (Brief 22). As to the first, Plaintiffs can comply with the Mississippi Law (just like the nine drug companies that have announced their voluntary compliance). But Plaintiffs prefer not to comply because their new restrictions on contract pharmacies have been extremely profitable. Any “harm” befalling Plaintiffs because of their deliberate violation of the Mississippi Law—which is presumed constitutional, see *White*, 2012 WL 3000645 at *2, and has not been adjudicated otherwise—is harm of Plaintiffs’ own making. As a matter of law, “self-inflicted harm is not irreparable.” *Texas v. U.S. Env’t Prot. Agency*, 662 F. Supp. 3d 739, 756 (S.D. Tex. 2023) (citing *Texas v. Biden*, 10

F.4th 538, 558 (5th Cir. 2021)). Thus, Plaintiffs’ prospective voluntary violation of the Mississippi Law cannot support preliminary injunctive relief.

Plaintiffs have also failed to establish irreparable harm that would be caused by *compliance* with the Mississippi Law. The only evidence they submit addressing this element is the Scheidler Declaration. Dkt. #8-1. Mr. Scheidler, however, merely states that “lost revenue will negatively impact AbbVie’s business model and affect its ability to invest in future products,” *id.* ¶ 22, and that “H.B. 728 threatens to impose significant penalties” if Plaintiffs do not comply, *id.* ¶ 23. Such conclusory assertions are insufficient to establish irreparable harm. “[A] general statement is not an adequate basis for relief on the ground of irreparable damages” predicated on compliance costs. *See State of California v. Latimer*, 305 U.S. 255, 260 (1938). Some “supporting detail or specification” is required. *See id.* “[C]onclusory and speculative allegations” will not suffice. *See Texas v. EPA*, 662 F. Supp. 3d at 756. *See also Division 80, LLC v. Garland*, No. 3:22-cv-148, 2022 WL 3648454, at *4 n.6 (S.D. Tex. Aug. 23, 2022) (rejecting allegations of “nebulous compliance costs” as insufficient to support preliminary injunction where no attempt was made “to quantify them with any specificity”).

Plaintiffs’ second irreparable harm argument—*viz.*, being “subject to an ongoing unconstitutional taking of private property”—is not evidence of any harm. It is simply Plaintiffs’ optimistic belief that they will prevail on the merits. To the extent that Plaintiffs’ profits will be impacted by the Mississippi Law, as explained below, monetary harm alone does not equate to irreparable harm. Plaintiffs also have not identified—nominally or otherwise—what “compliance costs” they allegedly will incur. Nor have they presented any evidence demonstrating that such costs are more than *de minimis*. On this record of generalized and conclusory assertions, this Court

is left with no evidentiary basis to support a finding of nonrecoverable compliance costs separate and apart from alleged financial losses.

Of course, Plaintiffs' contract pharmacy restrictions have been profitable for Plaintiffs and other pharmaceutical companies, and compliance with the Mississippi Law may render them less profitable. This again does not establish irreparable harm. "[A]s a general rule, a preliminary injunction is an inappropriate remedy where the potential harm to the movant is strictly financial." *Chambless Enters., LLC v. Redfield*, 508 F. Supp. 3d 101, 121 (W.D. La. 2020) (quoting *Atwood Turnkey Drilling, Inc. v. Petroleo Brasileiro, S.A.*, 875 F.2d 1174, 1179 (5th Cir. 1989)) (internal quotation marks omitted). "Even economic injuries that are substantial, in terms of money, time and energy necessarily expended in the absence of a stay, are not enough." *Id.* (quoting *Sampson v. Murray*, 415 U.S. 61, 90 (1974)) (internal quotation marks omitted). "[A]n exception to that rule exists where the potential economic loss is so great as to threaten the *existence* of the movant's business." *Air Prods. & Chems., Inc. v. Gen. Servs. Admin.*, No. 2:23-CV-147-Z, 2023 WL 7272115, at *13 (N.D. Tex. Nov. 2, 2023) (quoting *Atwood*, 875 F.2d at 1179) (internal quotation marks omitted) (emphasis in original). Where a plaintiff "fails to demonstrate financial harm that would threaten [its] existence," it "fails to establish irreparable harm." *See Andritz Sundwig GmbH v. United States*, Civil Action No. 4:18-2061, 2018 WL 3218006, at *10 (S.D. Tex. July 2, 2018). This doctrine applies even where the prospect of recoverable monetary relief is uncertain. *See Redfield*, 508 F. Supp. 3d at 121.

Plaintiffs have not and cannot demonstrate that compliance with the Mississippi Law threatens their very *existence*. According to AbbVie's 2023 Annual Report, the company reported annual net revenues of \$54.3 billion and net income of \$4.86 billion. *See* Def. Ex. C, at 56. Cash on hand at the end of FY 2023 totaled \$12.8 billion, and the company's total equity stood at \$10.4

billion. *Id.* at 58. AbbVie’s earnings were actually higher in 2021 and 2022 before it implemented the contract pharmacy restrictions. *Id.* at 56. Against this backdrop of considerable financial might, it can hardly be said that compliance with the Mississippi Law poses any threat to Plaintiffs’ financial viability—much less to its continued existence.

For all these reasons, Plaintiffs fail to make the requisite showing of irreparable harm, and their motion for preliminary injunction should be denied.

C. The harm to the State in granting an injunction would far exceed any purported harm to Plaintiffs, and the public interest thus favors denying Plaintiffs’ motion.

As noted above, the balance of the equities and the public interest “merge when the Government is the opposing party.” *Pacharne*, 565 F. Supp. 3d at 802 (quoting *Nken v. Holder*, 556 U.S. 418, 435 (2009)) (internal quotation marks omitted). “When a statute is enjoined, the State necessarily suffers the irreparable harm of denying the public interest in the enforcement of its laws.” *Robinson v. Ardoin*, 37 F.4th 208, 227 (5th Cir. 2022) (internal quotation marks omitted). *See also Texas Democratic Party v. Abbott*, 961 F.3d 389, 411 (5th Cir. 2020) (“[A]ny time a State is enjoined by a court from effectuating statutes enacted by representatives of its people, it suffers a form of irreparable injury.”) (internal quotation marks omitted). Even “the fact that compliance costs may be irreparable does not mean those costs automatically outweigh the harm that the requested injunctive relief would pose to the government or the public.” *Restaurant Law Ctr. v. U.S. Dep’t of Labor*, No. 1:21-CV-1106-RP, 2023 WL 4375518, at *14 (W.D. Tex. July 6, 2023).

On this element, the Court should first consider the laudatory purposes of the Mississippi Law. As explained above, the Mississippi Law promotes access to healthcare in four important ways. First, it prohibits certain discriminatory acts that discourage participation in the 340B program. Second, it restores wider geographic access to 340B drugs. Third, by eliminating

obstacles to the use of contract pharmacies, it restores 340B savings that 340B hospitals and clinics use to provide care to needy Mississippians who are unable to pay for their care. Fourth, by allowing greater use of contract pharmacies, it allows 340B hospitals and other Covered Entities to increase the number of patients who receive direct drug care benefits from the 340B entities. Again, contrary to Plaintiffs’ unsupported allegations, Mississippi 340B hospitals and other Covered Entities in many instances pass on 340B savings to 340B-qualified patients. Def. Exs. D, F, G. Thus, properly understood, the Mississippi Law fulfills an important public healthcare need.

Plaintiffs’ requested preliminary injunction would thwart the Legislature’s goal of promoting access to 340B pharmaceutical care, while simultaneously decreasing available healthcare to needy Mississippians. By way of example, a preliminary injunction would harm countless needy Mississippians served by the state’s largest hospital, the University of Mississippi Medical Center (“UMMC”) in Jackson. Defendant has submitted the declaration of Kelsey Raymer, PharmD, MHA, UMMC’s Assistant Director of Pharmacy Services – Specialty & Ambulatory Pharmacy. Def. Ex. D, ¶ 1. As Ms. Raymer explains, “UMMC is a Disproportionate Share Hospital (“DSH”), meaning that it serves a disproportionately large number of Medicare and Medicaid beneficiaries.” *Id.* at 2, ¶ 8. As a Covered Entity, UMMC uses 340B Program savings to support such patient-focused services as “uncompensated care, charity care, financial assistance, medication copy assistance, ambulatory pharmacy clinics, [and] medication therapy management services.” *Id.* at 3, ¶ 13. Because UMMC serves some of “the most vulnerable and marginalized members” of the community, it “depends upon the 340B program savings to continue to provide comprehensive healthcare services to Mississippians.” *Id.* at ¶ 14.

To ensure delivery and dispensing of 340B drugs to its qualifying patients, UMMC has, for many years, “maintained contractual relationships with numerous outside pharmacies.” *See*

id. at 1, ¶ 4. The continuation of delivery restrictions that Plaintiffs and other pharmaceutical manufacturers have imposed on such contract pharmacies in recent years “will have dire consequences for UMMC and its patients.” *See id.* at 3, ¶ 12. For instance, these restrictions often require qualifying 340B patients—who reside throughout the state—to physically travel to Jackson to have their 340B drug prescriptions filled at a UMMC in-house pharmacy. *See id.* Such travel is not a viable option for many patients, and because UMMC serves under-served and vulnerable patients without stable housing arrangements, mailing prescriptions is often not feasible. *See id.* “Being able to provide patients a local and convenient means to obtain prescriptions is paramount to UMMC’s ability to ensure all patients have access to affordable care.” *Id.* Plaintiffs’ and other drug manufacturers’ refusal to deliver to more than one contract pharmacy directly undermines that objective. It is critical that UMMC and its contract pharmacies—and by extension UMMC’s patients in need—receive the immediate relief that the Mississippi Law was intended to provide upon taking effect July 1. A preliminary injunction would disserve the public interest by elevating Plaintiffs’ interest in bolstering their astronomical profits over the medical needs of poor Mississippians while this litigation is pending.

Mississippi’s community hospitals will also be harmed by a preliminary injunction. Defendant has submitted the declaration of Kent Nicaud, President and CEO of Memorial Hospital Gulfport (“Memorial”), a public nonprofit medical complex jointly owned by the City of Gulfport and Harrison County. Def. Ex. E, ¶ 1. Memorial provides healthcare services to low-income patients, regardless of ability to pay, and is one of Mississippi’s largest providers of uncompensated patient care. *Id.* at 2, ¶ 6. As a Covered Entity, Memorial applies savings realized through the 340B Program to offset a portion of the deficit created by uncompensated patient care. *Id.* at ¶ 7. Specifically, “Memorial uses its 340B savings to fund hospital services, safety net

programs, increase the number of patients it serves, and expand and improve the services it provides its patients.” *Id.* The delivery restrictions that Plaintiffs and other pharmaceutical manufacturers have unilaterally imposed on Memorial’s use of contract pharmacies in the last three years have resulted in an 81% decrease (i.e., a \$30.4 million reduction) in annual 340B savings since FY 2020. *Id.* at ¶ 9. “Memorial depends upon the 340B program to operate at the level at which [it was] operating in FY 2020. Without that level of 340B savings, Memorial has had to reduce the services provided to patients.” *Id.* at ¶ 10. “[T]his situation will only worsen if the drug manufacturers are allowed to continue restricting the delivery and distribution of 340B drugs” dispensed through Memorial’s contract pharmacy arrangements. *Id.* Like UMMC, Memorial and its patients are in dire need of the relief the Mississippi Law is intended to provide.

As further evidence that a preliminary injunction would disserve the public interest, the Court should consider its effect on federally qualified Community Health Centers (“CHCs”). Defendant has submitted the declaration of Terrence Shirley, CEO of Community Health Center Association of Mississippi (“CHCAMS”). Def. Ex. F, ¶ 1. CHCAMS’s member CHCs provide comprehensive primary care to over 300,000 under-served Mississippians annually at hundreds of delivery sites across Mississippi. *See id.* at ¶¶ 1-2. Approximately 31% of Mississippi’s CHC patients are uninsured, while around 29% of Mississippi’s CHC patients are enrolled in Medicaid. *Id.* at ¶ 4. All of CHCAMS’s members are Covered Entities with contract pharmacy relationships. *Id.* at 2, ¶ 9. In 2022, Mississippi’s 21 CHCs received approximately \$76.5 million in federal grants, while providing sliding fee discounts to qualifying patients totaling approximately \$128.7 million. That same year, Mississippi’s CHCs received approximately \$43 million in savings and revenue from 340B drug discounts, “thereby recouping roughly 82% of the shortfall between their federal grant funding and the cost of uncompensated care they provide.” *Id.* at ¶ 8. Given the

types of patients that Mississippi’s CHCs serve, “they depend on the 340B drug program to operate.” *Id.* at ¶ 11. Because of manufacturer limitations on contract pharmacy arrangements, CHCAMS’s “members and their patients have already felt [the] impact” of lost 340B savings. *Id.* “[U]nless these limitations are checked and rolled back, this adverse impact will only worsen,” and access to healthcare will be diminished. *Id.*

Against the *possible* fractional losses Plaintiffs *may* incur, this Court must balance the continued real-world harm to Mississippi’s neediest citizens if enforcement of the Mississippi Law is enjoined. Upon any reasonable consideration of the relative equities, Plaintiffs’ claim that a preliminary injunction would serve the public interest rings hollow.

For all these reasons, Plaintiffs’ motion for preliminary injunction should be denied.

II. IF THE COURT GRANTS A PRELIMINARY INJUNCTION, IT SHOULD BE APPROPRIATELY LIMITED IN SCOPE.

The Constitution and equitable principles dictate that injunctive relief must be “tailored to redress” a “particular injury.” *Gill v. Whitford*, 585 U.S. 48, 73 (2018). And equity requires that injunctive relief be no broader than “necessary to provide complete relief *to the plaintiffs*.” *See Madsen v. Women’s Health Ctr., Inc.*, 512 U.S. 753, 765 (1994) (internal quotation marks omitted) (emphasis added). “The purpose of a preliminary injunction is always to prevent irreparable injury.” *Canal Auth. of State of Fla. v. Callaway*, 489 F.2d 567, 576 (5th Cir. 1974).

Further, it is well settled that “the scope of injunctive relief is dictated by the extent of the violation established,” and that a “court must narrowly tailor an injunction to remedy the specific action which gives rise to the order.” *Green Valley Special Util. Dist. v. City of Schertz, Tex.*, 969 F.3d 460, 478 n.39 (5th Cir. 2020) (internal quotation marks omitted). An injunction cannot “encompass more conduct than was requested or exceed the legal basis of the lawsuit.” *Scott v. Schedler*, 826 F.3d 207, 214 (5th Cir. 2016). *See also E.T. v. Paxton*, 19 F.4th 760, 769 (5th Cir.

2021) (same). Generally, “injunctive relief should be no more burdensome to the defendant than necessary to provide complete relief to the plaintiffs.” *Lion Health Servs., Inc. v. Sebelius*, 635 F.3d 693, 703 (5th Cir. 2011) (internal quotation marks omitted). As a matter of law pursuant to FRCP 65, a preliminary injunction is only binding upon the parties; their respective officers, agents, employees, and attorneys; and those acting in concert with them. FED. R. CIV. P. 65(d)(2).

If the Court is inclined to grant a preliminary injunction, any relief should be limited to the named plaintiffs. This is not a class action, nor do Plaintiffs seek to make it one. A preliminary injunction granted only as to the named plaintiffs would provide full relief. Any injunction should be narrowly tailored to enjoin the enforcement of H.B. 728 against the named plaintiffs. It should not be so broad as to apply to non-plaintiffs. Defendant respectfully submits that any broader injunction would exceed the bounds of this Court’s jurisdiction under Article III and the limitations of equitable relief.

CONCLUSION

In the end, Plaintiffs’ preemption claims have already been decided by this Court in the *Novartis* and *PhRMA* companion cases and by the Eighth Circuit in *McClain*. Plaintiffs’ takings claims are contrary to overwhelming case law, including controlling Fifth Circuit precedent. For all these reasons, the Court should deny Plaintiffs’ motion for a preliminary injunction [Dkt. #8] in its entirety.

THIS the 8th day of July 2024.

Respectfully submitted,

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DEFENDANT

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CERTIFICATE OF SERVICE

I, Rex M. Shannon III, Special Assistant Attorney General and one of the attorneys for Defendant Lynn Fitch, in her official capacity as Attorney General of Mississippi, do hereby certify that I have this date caused to be filed with the Clerk of the Court a true and correct copy of the above and foregoing via the Court's ECF filing system, which sent notification of such filing to all counsel of record.

THIS the 8th day of July 2024.

s/Rex M. Shannon III
REX M. SHANNON III